

REMARKS

Claims 1-41 were pending in the present application. Claims 7-9 and 32-41 have been withdrawn from consideration. Accordingly, claims 1-6 and 10-31 are currently under consideration. By virtue of this response, claim 19 has been amended. Claim 19 was amended per the Examiner's suggestion for clarity regarding the recitation of the claim dependencies. To facilitate prosecution only, claim 19 was also amended to recite that the library is stored on computer readable media. Support for this amendment may be found throughout the specification. For example, support may be found at page 4, lines 10-21 and page 38, lines 4-8. Therefore, no new matter has been added by these amendments.

With respect to all amendments and cancelled claims (and/or subject matter related thereto), Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any such subject matter in future continuation and/or divisional application.

Reconsideration and allowance of the pending claims in view of the remarks presented herein is respectfully requested.

Objection to Claim 19

The Examiner has objected to claim 19 because of an alleged informality. Applicant has amended claim 19 per the Examiner's suggestion to correct the informality. Accordingly, withdrawal of this objection is respectfully requested.

Rejection under 35 USC § 101

The Examiner has rejected claims 19 and 20 as allegedly directed to non-statutory subject matter. While not acquiescing to the Examiner's rejection, and only for the purpose of facilitating prosecution, Applicant has amended claim 19 to recite that the library is stored on a

computer readable media. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejections under 35 USC § 112

The Examiner has rejected claims 19 and 20 as failing to comply with the written description requirement. The Examiner alleges that “[t]he claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.” (Office Action, page 3). Applicant traverses this rejection for the reasons presented herein below.

The Examiner contends that that “an adequate written description of a molecular profile requires more than a mere statement that it is part of the invention and reference to a potential method of producing it”. (Office Action, page 6) Applicant respectfully submits that the instant specification fully complies with the written description requirement. Applicant notes that claims 19-20 are product by process claims. Accordingly, Applicant does not need to define the products in terms of structural characteristics. See, e.g., Atlantic Thermoplastics v. Fayatex Corp., 970 F.2d 834, 844 (Fed. Cir. 1992). Withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 1-6 and 10-31 as failing to comply with the enablement requirement. The Examiner contends that “[t]he claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.” (Office Action, page 7). Applicant traverses this rejection for the reasons provided herein below.

Contrary to the Examiner’s contention, Applicant respectfully submits that one of skill in the art could make and/or use the claimed invention without undue experimentation. The instant disclosure provides ample and detailed guidance on preparing and culturing the liver stem cells (LSC) (e.g., pages 16-21), contacting the LSC cells with a chemical composition of predetermined or unknown toxicity (e.g., pages 22-23), detecting alterations in levels of gene or protein expression

(e.g., pages 25-34), collecting and correlating the molecular profiles (e.g., pages 34-36), typing and ranking a test chemical composition (pages 37-45 and Examples) and examples of chemicals of predetermined toxicities that may be utilized (pages 13-16). Accordingly, Applicant respectfully submits that the guidance provided is more than adequate to allow one of ordinary skill to practice the claimed invention.

In effect, Applicant respectfully submits that the Examiner has not met his burden of providing evidentiary support for the alleged non-enablement of the instant disclosure. In re Marzocchi, 439 F2d 220; 169 USPQ 367 (CCPA 1967). Accordingly, withdrawal of this ground of rejection is respectfully requested.

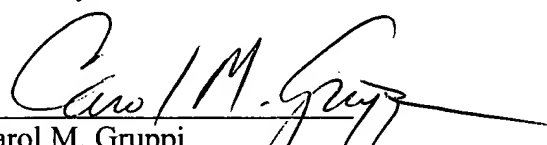
CONCLUSION

Applicants have, but way of the amendments and remarks presented herein, addressed all issues that were raised in the outstanding Office Action. Applicant respectfully contends that this Amendment has overcome the rejections and that the pending claims are in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **441472000500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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